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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/297,733	07/01/1999	Catia BASTIOLI	C13929/11003	1198
7590 02/16/2006		EXAMINER		
BRYAN CAVE LLP			NUTTER, NATHAN M	
1290 Avenues of the Americas New York, NY 10104			ART UNIT	PAPER NUMBER
,			1711	
			DATE MAILED: 02/16/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	<u> </u>
	09/297,733	BASTIOLI ET AL.	
Office Action Summary	Examiner	Art Unit	
	Nathan M. Nutter	1711	
The MAILING DATE of this communication appeariod for Reply	pears on the cover sheet w	vith the correspondence address	
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D  - Extensions of time may be available under the provisions of 37 CFR 1.1  after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period  - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailin earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUN 136(a). In no event, however, may a will apply and will expire SIX (6) MO te, cause the application to become A	ICATION. reply be timely filed  NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133).	
Status			
1) Responsive to communication(s) filed on 01 E	December 2005.		
	s action is non-final.		
3) Since this application is in condition for allowated closed in accordance with the practice under	•	·	
Disposition of Claims			
4) ☑ Claim(s) 1-18 and 20-23 is/are pending in the 4a) Of the above claim(s) 20-22 is/are withdray  5) ☐ Claim(s) is/are allowed.  6) ☑ Claim(s) 1-18 and 23 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or	wn from consideration.		
Application Papers			
9) The specification is objected to by the Examine	er.		
10) ☐ The drawing(s) filed on is/are: a) ☐ acc			
Applicant may not request that any objection to the			
Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E	•		
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureat* See the attached detailed Office action for a list	nts have been received. Its have been received in only documents have bee au (PCT Rule 17.2(a)).	Application No n received in this National Stage	
Attachment(s)  1) X Notice of References Cited (PTO-892)	4) 🗖 Intention	Summary (PTO-413)	
<ul> <li>Notice of References Cited (PTO-692)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08 Paper No(s)/Mail Date</li></ul>	Paper No	(s)/Mail Date Informal Patent Application (PTO-152)	

#### **DETAILED ACTION**

This application has been re-assigned to Examiner Nathan M. Nutter in Art Unit 1711. All inquiries regarding this application should be directed to Examiner Nutter at telephone number 571-272-1076.

#### Response to Amendment

In response to the amendment 1 December 2005 the following is being placed in effect.

The objection to claims 5, 7, 8, 9, 1 2, 13 and 14 and 16 under 37 CFR 1 .75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim is hereby expressly withdrawn.

The rejection of claims 17-19 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby expressly withdrawn.

The rejection of claims 17-19 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, is hereby expressly withdrawn.

The rejection of claims 1, 2 and 6 under 35 U.S.C. 1 12, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby expressly withdrawn.

The inclusion of an Abstract is noted.

Upon review of the application, it was determined that a restriction of inventions would be necessary, as follows.

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#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-18 and 23, drawn to a biodegradable heterophase composition comprising a thermoplastic starch and a thermoplastic polymer incompatible with starch and an interfacial agent having an HLB greater than 8 and is obtained from a carboxylic acid having a dissociation constant pK lower than 4.5, classified in class 524, subclasses 47+.
- II. Claims 20-22, drawn to a biodegradable heterophase composition comprising a thermoplastic starch and a thermoplastic polymer incompatible with starch, wherein the starch has a "microstructure in which at least 80% of the particles have dimensions smaller than 1 μm, classified in class 524, subclasses 47+.

The inventions are independent or distinct, each from the other because:

Inventions of Group I and of Group II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different compositions (Group I requires an interfacial agent), and would produce different effects as a result. Further, the Group II claims require the thermoplastic starch to be in defined sizes as the dispersed component. This would also produce a different effect.

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Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Kevin Hooper on 14 February 2006 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-18 and 23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-22 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-18 and 23 will be examined.

### Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 13-18 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krishnan et al (WO 95/24447), previously cited.

The reference to Krishnan et al (WO 95/24447) discloses the manufacture of compatibilized blends of a biodegradable hydrophobic polyester, unmodified starch or other similar polysaccharide, other biodegradable polymers, plasticizers and additives. The polymer forms a continuous phase while starch forms a discontinuous phase. A preferred biodegradable polymer is poly (E-caprolactone) at page 7 (line 20). Organic plasticizers, including esters of polyols are included in the blend at page 15, (lines 21-30). Compatibilizers are also taught for employment at page 13 (lines 18-35).

Also included in the blend may be certain additives that function as binders by complexing with starch at page 19 (lines 10-16), including monoglycerides. The reference teaches the use of the composition in melt processing methods, including blow molding, which produces films and packaging materials, as recited in claims 16-18 at page 6 (lines 13-32)

While Krishnan et al do not specifically mention the (claimed) dissociation constant pK as lower than 4.5, the instant Specification discloses the use of esters of acetic acids as usable therein at the paragraph bridging pages 5 and 6, which are identical to those disclosed herein at page 15 (lines 21-30). Further, although Krishnan et al do not disclose the specific hydrophilic lipophilic balance index value (HLB) of the ester, since the reference broadly teaches the (claimed) glycerides, it is reasonable to assume that the glycerides of Krishnan et al possess this properties. Therefore it would have been obvious to follow teachings of Krishnan et al and arrive at the instant invention. Since no criticality has been established for claimed pK to be lower than 4.5 and HLB to be greater than 8, the instant claims are deemed to be prima facie obvious over Krishnan et al.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

<sup>(</sup>b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-18 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Bastioli et al (WO 94/03543), previously cited.

The patent to Bastioli et al (WO 94/03543) shows the contemplated invention at the Abstract and the claims.

Claims 1-18 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Bastioli et al (US 5,874,486), newly cited

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Note the claims.

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Claims 1-18 and 23 are rejected under 35 U.S.C. 102(e) as being anticipated by Bastioli et al (US 5,874,486), newly cited

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Note the claims and column 4 (lines 11-23).

# Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,348,524. Although the conflicting claims are not identical, they are not patentably distinct from each other because the term plasticizer, recited in the patented claims, would embrace the constituents recited herein as an interfacial agent.

Claims 1-18 and 23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of copending Application No. 09/335,238. Although the conflicting claims are not identical, they are not patentably distinct from each other because the term plasticizer, recited in the copending application claims, would embrace the constituents recited herein as an interfacial agent.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-18 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 5,874,486. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inclusion of a composition of a dispersed starch in a continuous polymer phase is within the recitations of the patented claims. Further, the specific fluidizing (interfacial) agents recited in the patented claims embrace those esters as recited and claimed herein. The agents may have the identical physical characteristics

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recited herein. Note column 4 (lines 11-23) which teaches the identical esters as employed herein.

Claims 1-18 and 23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,277,899. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inclusion of a composition of a dispersed starch in a continuous polymer phase is within the recitations of the patented claims. Further, the specific fluidizing (interfacial) agents recited in the patented claims embrace those esters as recited and claimed herein. The agents may have the identical physical characteristics recited herein. Note the paragraph bridging column 3 to column 4 which teaches the identical esters as employed herein.

#### Response to Arguments

Applicant's arguments filed 1 December 2005 have been fully considered but they are not persuasive.

Applicants argue that the dissociation constant pK of the Krishnan et al reference would not be embraced by the specific glycerol acetates disclosed at page 15 (lines 21-30). It is pointed out to applicants that the paragraph bridging page 5 to page 6 of the instant Specification teaches the employment of esters of glycerol with acetates. The fact that one inventor characterizes a constituent in a way that differs from applicant's

method of characterization is not sufficient to remove the grounds of rejection. The inclusion of the constituent is sufficient.

Due to the new grounds of rejection, this Office Action is not being made FINAL.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan M. Nutter whose telephone number is 571-272-1076. The examiner can normally be reached on 9:30 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James J. Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

Nathan M. Nutter Primary Examiner Art Unit 1711

nmn

14 February 2006